EXHIBIT A

DECLARATION of DANIEL A. BLOCH

I, Daniel A. Bloch, of the City of Tucson, in the state of Arizona, declare as follows:

I am an Emeritus Professor in the Department of Health Research and Policy, Division of Biostatistics at Stanford University, Stanford, California. I was appointed Associate Professor in 1993, Full Professor in 2001 and have been emeritus since 2007.

My primary interests include application of mathematical statistics to scientific studies and to advance bio-statistical research methodology. I have published 196 original articles in peer-reviewed journals and have an additional eight articles either in press or submitted for publication. Approximately 170 of these articles have appeared in medical journals, mostly co-authored with medical faculty at Stanford and at other universities in the United States, Canada and Europe. Often these collaborations have afforded me the opportunity to explore the application of recently developed statistical methods by illustrating their use on real data, and to explore the development of new statistical methods. Among the several dozen articles devoted to statistical methods, topics include efficiency and the bias of estimators, sample size estimation, kappa statistics, non-parametric statistics, methods of assessing multi-parameter endpoints, and other topics.

I am particularly experienced in applying statistics to the rheumatic diseases. I have co-authored well over 30 articles in *Arthritis and Rheumatism* and 25 articles in the *Journal of Rheumatology*, considered by many to be among the leading specialized peer-reviewed journals for these fields of medicine. I have been statistical reviewer for dozens of medical journals, including most journals in Europe, Canada and the U.S. that specialize in arthritis and rheumatism. I have been a member of numerous data safety and monitoring boards for

studies of new agents to treat these diseases. Most recently, I participated in an ongoing US Food & Drug Administration (FDA) initiative seeking information on issues related to clinical development programs for human drugs, biological products, and medical devices for the treatment and prevention of osteoarthritis. Specifically, I served as Chair of the "Statistical Considerations" working group for the Osteoarthritis Society International (OARSI) proposal accepted by the FDA. I believe that recognition of my expertise as a statistical researcher and at-large applicator to diverse fields of medicine are behind a recent Nobel Prize committee's invitation to me to provide nominations for the Nobel Prize in Medicine.

I have extensive teaching experience, having taught courses offered by both the Mathematical Statistics and the Health Research and Policy departments at Stanford. Before becoming emeritus, at Stanford I supervised the statistical efforts of numerous post-doctoral fellows and medical students. I have also been invited to give dozens of bio-statistical presentations, in such diverse settings as Harvard, The Johns Hopkins University, the FDA Center for Biologics Evaluation and Research, the College of Problems for the Drug Dependence and the American College of Rheumatology annual meetings and at Institute of Mathematical Statistics meetings.

Since 1987 I have been a consultant on an ad hoc basis to pharmaceutical and biotechnical firms, including both start-up and established companies. Herein I participate in all aspects of applying statistics to implement investigational plans; e.g.: for protocol development, design of trials, data base design, and analysis. I continue to serve on numerous data safety monitoring boards and have been a member of the FDA Statistical Advisory Panel. I attach

as Exhibit 1 my *curriculum vitae* which sets out, in greater detail, my professional qualifications.

The Present Case

I have been retained by the law firm of Coughlin, Stoia, Geller, Rudman & Robbins, counsel for plaintiffs in a securities class action against Rigel Pharmaceuticals, Inc, to provide expert opinion and comments with regard to data interpretation, reporting and use of statistics in (a) the December 13, 2007 press release issued by Rigel, in (b) the ACR20, ACR50 and ACR70 summary data per Country and US/Mexico combined, dated October, 2008, and in (c) the Weinblatt et al article published in *Arthritis and Rheumatism* in November, 2008. In this regard I was given a copy of the Class Action Consolidated Complaint demanding a trial by jury, dated July 14, 2009.

Comments on Rigel's December 13, 2007 Press Release "Efficacy Results."

1. Rigel announced "R788 has demonstrated statistically significant results in treated Rheumatoid Arthritis…" and that " Groups treated …at 100mg and 150mg…showed higher ACR20, ACR50, ACR70 and DAS28 response rates than the placebo group." However, the reported achieved levels of statistical significance (p-values) were not adjusted for the multiple pair-wise comparisons performed by Rigel. At a minimum, 16 comparisons were performed: for each the of three doses, comparisons were performed of each of the four outcome variables to Placebo (12 comparison) and comparisons were performed between 100mg and 150mg dose groups of each of the four outcome variables (4 comparisons). Since we are not told if the 50mg group was to be compared to either of the other two higher dose groups, I do not know if an additional 8 comparisons were performed but I suspect the intent was to make these comparisons as well. A person skilled in the art of applied statistics

understands that when multiple comparisons are performed, an actual p-value is greater than the nominal, unadjusted value. The most common method to adjust p-values is the Bonferroni method---with this method each nominal p-value is multiplied by the number of comparisons. Applying this method to the nominal p-values included in the December 13, 2007 Efficacy Results table, among the eight comparisons with nominal p-values< 0.05 only six are significant after adjusting for 16 comparisons. The ACR20 100mg comparison to Placebo and the DAS28-CRP 100mg comparison to Placebo are not statistically significant at the 5% significance level.

2. I have verified that the 6 nominal p-values reported in the Efficacy Results table for the 6 ACR comparisons are correct with applications of the chi-square test for 2X2 contingency tables. However, when chi-square tests are applied to the DAS28-CRP data, one learns that both of the nominal reported p-values are not correct. The correct nominal p-values are p=0.049 (not 0.005 as reported) for comparing DAS28-CRP 100mg results to the Placebo group and p=0.002 (not <0.001) for comparing DAS28-CRP 150mg results to the Placebo group.

3. Methods other than the Bonferroni method could be employed to adjust for multiple comparisons. One method is the Tukey Method of Multiple Comparisons which makes reference to the Studentized Range distribution. Tukey's method adjusts the achieved significance level for all possible pair-wise comparisons that could be made among groups. Upon applying Tukey's Studentized Range test to the 189 patients among 4 dose groups with data recorded for ACR20, one learns that the ACR20 100mg comparison to Placebo is significant at the p=0.03 level and the 150mg comparison to Placebo is significant at the p=0.004 level. Here, each p-value has been adjusted for 6 different pair-wise comparisons. However, the results of applying Tukey's Studentized Range test separately to each Country's ACR20 Data clearly show these p-values are incorrect because of the distortion of the

results created by combining data from the U.S. and Mexico. In fact, neither the ACR20 100mg comparison to Placebo nor the ACR20 150mg comparison to placebo is statistically significant. These results are presented below.

Comments on Rigel's October 27, 2008 Report of ACR Response Data by Country

1. **Pooling the U.S. and Mexico data rather than combining each country's separate results is not appropriate**

Inspection of the ACR rates by Country easily reveals that the analysis of the combined data from the U.S. and Mexico reported with the December 13, 2007 press release is not appropriate and resulted in misleading success rates and false p-values. Specifically, Defendant failed to account for the fact that patients in Mexico had higher success rates in all treatment groups than the U.S patient groups. Because the Defendant did not report an analysis which adjusts for these large differences in success rates between countries, the results presented in Rigel's December 13, 2007 Press Release bias results in favor of R788.

Two examples are as follows: (1) Referencing the patient populations who received the 150mg dose or Placebo and were assessed for response with the ACR20, the primary outcome variable, the differences in response rates of the 150mg group verses the Placebo group were 16% and 21% in the U.S. and Mexico, respectively. However, the difference reported with the December 13, 2007 press release is 34%, a success rate over twice that achieved in the U.S and 13% higher than that achieved in Mexico. (2) Referencing the patient populations who received the 50mg dose or Placebo and were assessed for response with the ACR20, the primary outcome variable, the differences in success rates of the 50mg

group verses the Placebo group was 9% in the U.S. No such comparison can be made for patients treated in Mexico since no patients received the 50mg dose in Mexico. However, the difference reported with the December 13, 2007 press release is -5%, a difference in success rates which is 14% lower than that achieved in the only country that gave patients the 50mg dose, the U.S. These examples illustrate that the data from the U.S and Mexico should not pooled, and that a proper, overall, analysis must combine the results of pair-wise comparisons obtained from each country.

This led me to perform the following series of analyses: 1) Perform chi-square tests separately for each Country, 2) Combine the nominal p-values obtained from the separate chi-square tests across Countries to obtain an overall nominal p-value, adjusted for Country, 3) Perform Fisher Exact tests to the 2X2 Contingency table data, 4) Combine the nominal p-values obtained from the separate Fisher Exact tests across Countries to obtain an overall nominal p-value, adjusted for Country, 5) Apply Tukey's Studentized Range test separately to each Country's ACR20 data. Chi-square tests were performed because they were the statistical tests performed by the defendants, but I applied them separately to each country's data. Fisher's Exact tests were performed because often use of a chi-square test was not statistically justifiable. I used a second method developed by Fisher, Fisher's procedure to combine p-values from 2 independent studies, in order to obtain an accurate p-value for the combined results from the U.S. and Mexico. I applied Tukey's Studentized Range test to ACR20 success rates, the primary outcome variable, in order to address the multiple comparisons problem. This is a basic set of analyses applying standard statistical methodologies.

2. **The Fisher Exact test**

Fisher's Exact test is a non-parametric test that does not rely on asymptotic Normality assumptions, as does the chi-square test. It is most useful when at least one of the sample

sizes in the 2X2 contingency table is so small that the chi-square test should not be used. Two criteria that are often employed are to require using a test such as the Fisher Exact test (i) if the expected cell frequency of the smallest entry in the 2X2 table is less than 5 {Reference Fleiss, page 25}, and (ii) if the smallest entry in the 2X2 table is less than 20 {Reference Moses, page 231}. Because of it's computational simplicity, a modified version of the chi-square test, often called the Yates chi-square test {Reference Moses, pages 234-5}, is often employed instead of Fisher's Exact test. In what follows I do not report on results obtained using the Yates chi-square test because results were close to those obtained with Fisher's Exact test.

3. **Results of performing chi-square tests separately for each Country**

(A) ACR20: Comparison of 100mg dose to Placebo. The nominal p-values obtained by applying separate chi-square tests to the U.S data and to the Mexico data are 0.047 and 0.130, respectively. Using Fisher's procedure to combine p-values from 2 independent studies, the overall nominal p-value equals 0.037. The nominal p- value of 0.008 reported with the December 13, 2007 press release is false. Since the smallest frequency in both the U.S. and Mexico 2X2 data tables is less than 20, Fisher's Exact test results are presented below.

(B) ACR20: Comparison of 150mg dose to Placebo. The nominal p-values obtained by applying separate chi-square tests to the U.S data and to the Mexico data are 0.460 and 0.076, respectively. Using Fisher's procedure to combine p-values from 2 independent studies, the overall nominal p-value equals 0.152. The nominal p-value of <0.001 reported with the December 13, 2007 press release is false and the correct conclusion is that success rates between the 150mg and Placebo groups are not statistically significantly different.

Additionally, since the smallest frequency in both the U.S. and Mexico 2X2 data tables is less than 20, Fisher's Exact test results are presented below.

(C) ACR50: Comparison of 100mg dose to Placebo. The nominal p-values obtained by applying separate chi-square tests to the U.S data and to the Mexico data are 0.021 and 0.050, respectively. Using Fisher's procedure to combine p-values from 2 independent studies, the overall nominal p-value equals 0.003. The nominal p-value of 0.002 reported with the December 13, 2007 press release is false. However, since the smallest expected cell frequency of the U.S. data is 3.8 and the smallest frequency in both the U.S. and Mexico 2X2 data tables is less than 20, Fisher's Exact test results are presented below.

(D) ACR50: Comparison of 150mg dose to Placebo. The nominal p-values obtained by applying separate chi-square tests to the U.S data and to the Mexico data are 0.014 and 0.078, respectively. Using Fisher's procedure to combine p-values from 2 independent studies, the overall nominal p-value equals 0.026. The nominal p- value of <0.001 reported with the December 13, 2007 press release is false. However, since the smallest expected cell frequency of the U.S. data is 2.5 and the smallest frequency in both the U.S. and Mexico 2X2 data tables is less than 20, Fisher's Exact test results are presented below.

(E) **ACR70**: Comparison of 100mg dose to Placebo. The nominal p-values obtained by applying separate chi-square tests to the U.S data and to the Mexico data are 0.051 and 0.004, respectively. Using Fisher's procedure to combine p-values from 2 independent studies, the overall nominal p-value equals 0.0006. However, because the smallest expected cell frequency of the U.S. data is 1.6 and the smallest frequency in both the U.S. and Mexico 2X2 data tables is less than 20, Fisher's Exact test results are presented below.

(F) ACR70: Comparison of 150mg dose to Placebo. The nominal p-values obtained by applying separate chi-square tests to the U.S data and to the Mexico data are 0.001 and

0.009, respectively. Using Fisher's procedure to combine p-values from 2 independent studies, the overall nominal p-value equals 0.0001. However, because the smallest expected cell frequency of the U.S. data is 1.7 and the smallest frequency in both the U.S. and Mexico 2X2 data tables is less than 20, Fisher's Exact test results are presented below

(G) Summary of Results of performing chi-square tests separately for each Country

The overall nominal p-values are higher than those reported with the December 13, 2007 press release, even without accounting for multiple comparisons. The overall nominal p-values comparing both 100mg and 150mg groups to Placebo for the primary outcome variable, the ACR20, and the overall nominal p-value comparing the 150mg group to Placebo for the ACR50 are much bigger than those reported with the December 13, 2007 press release. Since in all instances p-values obtained using the ordinary chi-square are questionably valid, Fisher's Exact test is the preferred statistical method.

4. **Results of performing Fisher Exact tests separately to each Country**

As pointed out in the previous section, Fisher Exact test rather than a chi-square test is the appropriate statistical procedure.

(A) ACR20: Comparison of 100mg dose to Placebo. The nominal p-values obtained by applying separate Fisher Exact tests to the U.S data and to the Mexico data are 0.068 and 0.1474, respectively. Using Fisher's procedure to combine p-values from 2 independent studies, the overall nominal p-value equals 0.056. The nominal p-value of 0.008 reported with the December 13, 2007 press release is false. The conclusion is that success rates between the 100mg and Placebo groups are not statistically significantly different.

(B) ACR20: Comparison of 150mg dose to Placebo. The nominal p-values obtained by applying separate Fisher Exact tests to the U.S data and to the Mexico data are 0.589 and 0.094, respectively. Using Fisher's procedure to combine p-values from 2 independent

studies, the overall nominal p-value equals 0.216. The nominal p-value of <0.001 reported with the December 13, 2007 press release is false. The conclusion is that success rates between the 150mg and Placebo groups are not statistically significantly different.

(C) ACR50: Comparison of 100mg dose to Placebo. The nominal p-values obtained by applying separate Fisher Exact tests to the U.S data and to the Mexico data are 0.037 and 0.086, respectively. Using Fisher's procedure to combine p-values from 2 independent studies, the overall nominal p-value equals 0.022. . The nominal p-value of 0.002 reported with the December 13, 2007 press release is false. If adjusted for multiple comparisons, the success rates between the 100mg and Placebo groups are not statistically significantly different.

(D) ACR50: Comparison of 150mg dose to Placebo. The nominal p-values obtained by applying separate Fisher Exact tests to the U.S data and to the Mexico data are 0.064 and 0.1144, respectively. Using Fisher's procedure to combine p-values from 2 independent studies, the overall nominal p-value equals 0.043. The nominal p-value of <0.001 reported with the December 13, 2007 press release is false. If adjusted for multiple comparisons, the success rates between the 150mg and Placebo groups are not statistically significantly different.

(E) **ACR70**: Comparison of 100mg dose to Placebo. The nominal p-values obtained by applying separate Fisher Exact tests to the U.S data and to the Mexico data are 0.088 and 0.005, respectively. Using Fisher's procedure to combine p-values from 2 independent studies, the overall nominal p-value equals 0.004. The nominal p-value of <0.001 reported with the December 13, 2007 press release is false.

(F) ACR70: Comparison of 150mg dose to Placebo. The nominal p-values obtained by applying separate Fisher Exact tests to the U.S data and to the Mexico data are 0.023 and

0.01, respectively. Using Fisher's procedure to combine p-values from 2 independent studies, the overall nominal p-value equals 0.002. The nominal p-value of <0.001 reported with the December 13, 2007 press release is false.

(G) Summary of Results of performing Fisher Exact tests separately for each Country

The combined p-values attained with using Fisher Exact tests are more accurate than those using chi-square tests. The overall nominal p-values are higher than those reported with the December 13, 2007 press release, even without accounting for multiple comparisons. Of note, not only are the overall nominal p-values comparing both 100mg and 150mg groups to Placebo for the primary outcome variable, the ACR20, much bigger than those reported with the December 13, 2007 press release, the conclusion is that success rates between either high dose group and Placebo are not statistically significantly different. This conclusion is supported with the application of Tukey's Studentized Range tests to the ACR20 outcome data. The results obtained with Tukey's Studentized Range tests are presented in the next section.

Results of applying Tukey's Studentized Range test separately to each Country's ACR20 Data.

The purpose of applying Tukey's Studentized Range test separately to each country's data and then combining the test results to obtain overall p-values is to obtain valid p-values, having adjusted for differences between U.S and Mexico and to account for the multiple pair-wise comparisons performed by Rigel. Upon applying Tukey's Studentized Range test to the 97 U.S. patients among 4 dose groups with data recorded for ACR20, one learns that the ACR20 100mg comparison to Placebo is not significant with p=0.191 and the 150mg

comparison to Placebo is not significant with p=0.902. Here p-values have been adjusted for 6 different pair-wise comparisons. Upon applying Tukey's Studentized Range test to the 92 Mexico patients among 3 dose groups with data recorded for ACR20 (Mexico did not treat patients with the 50mg dose), one learns that the ACR20 100mg comparison to Placebo is not significant with p=0.259 and the 150mg comparison to Placebo is not significant with p=0.172. Here p-values have been adjusted for 3 different pair-wise comparisons. Using Fisher's procedure to combine the p-values from the U.S. and Mexico, the overall p-values equal 0.198 and 0.444 when the 100mg and 150mg group success rates are compared to Placebo success rates, respectively.

Summary of results of applying Tukey's Studentized Range test separately to each country's ACR20 data

With this analysis I have controlled for differences between U.S and Mexico and for multiple pair-wise comparisons that were made between groups. The overall p-values comparing both 100mg and 150mg groups to Placebo for the primary outcome variable, the ACR20, are large and the correct conclusion is that success rates between either of the high dose groups and Placebo are not statistically significantly different. The nominal p-values reported with the December 13, 2007 press release are false and misleading.

Summary Comments Based on Proper Statistical Analyses Allowed with Rigel's October 27, 2008 Report of ACR Response Data by Country

When the data is properly analyzed, all of the nominal p-values are higher than those reported with the December 13, 2007 press release, even without accounting for multiple

comparisons. The comparisons of both 100mg and 150mg groups to Placebo for the primary outcome variable, the ACR20, with or without accounting for multiple comparisons, are not statistically significant.

Weinblatt et al article published in *Arthritis and Rheumatism* , November, 2008

In addition to the failures of statistical analyses revealed by my re-calculation of all of the p-values reported with Rigel's December 13, 2007 press release of "Efficacy Results" and revealed with my analysis allowed with Rigel's October 27, 2008 report of ACR response data by country, the statistical analysis in the *Arthritis and Rheumatism* publication also contains errors. As did Rigel's December 13, 2007 report of "Efficacy Results," the errors in this article skew results in favor of R788. In my opinion, the incorrect and misleading presentation of study design and faulty analyses cast the efficacy of R788 in an overly optimistic light. In what follows I will first provide a brief summary defining the statistical concepts of "level of significance" and "power" of a statistical test. With this background, I will support my contentions in subsequent comments.

Significance level, one-sided and two-sided tests, and the power of a statistical test

(A) Significance level. There are two kinds of error one must guard against in designing a study comparing drug groups. The first error, called the Type I error, occurs when one states the difference in success rates between groups is real when in fact the difference is zero. This error is controlled during the planning phase of the study by choosing the significance level of the test, denoted by α , to be small, typically not greater than 5%. The results of the study are "statistically significant" if the observed difference between the success rates of the two groups is sufficiently large so that the p-value derived from

applying the statistical test is not greater than α. In what follows I set α =5%, the significance level reportedly used by Rigel in planning their study.

(B) One-sided and two-sided tests. Let s_1 and s_2 denote the observed success rates of the two drugs to be compared. The percentages s_1 and s_2 estimate the underlying (but unknown) success rates in the entire population who could receive either drug. Denote these hypothetical population success rates by S_1 and S_2. If the difference in rates is not zero and the Investigator hypothesizes that the difference in rates can only occur in one direction, say S_2 must be greater than S_1, then a one-sided test is performed. The test will be "statistically significant" at the 5% level of significance only if s_2 is sufficiently greater than s_1 so that the p-value from the test is not more than 5%. With a two-sided test, "statistical significance" is achieve if either s_2 is sufficiently greater than s_1 or if s_1 is sufficiently greater than s_2. The significance level of 5% is divided in two, so that the p-value must not exceed 2.5% if s_2 is sufficiently greater than s_1 or not exceed 2.5% if s_1 is sufficiently greater than s_2. For any given comparison between drug groups, only one of these possibilities can occur (either s_2 is greater than s_1 or s_1 is greater than s_2). All of the p-values reported with Rigel's December 13, 2007 report of "Efficacy Results" and reported by Weinblatt et al in the *Arthritis and Rheumatism* publication are two-sided.

A one-sided test is called for only if there is no interest in a difference in the reverse direction. However, for the Rigel study results an analyst is ethically required to perform two-sided tests, for if the data should reveal that the group receiving the active drug

compound did worse than the Placebo group, this result must be reported. This conclusion can only be reached with a two-sided test.

(C) Power of a statistical test

The second kind of error, called the Type II error, occurs when one fails to find that the difference in success rates between groups is real when in fact the difference is real. How large a difference is "real" is a clinical judgment of what is minimally important to detect. This error is controlled during planning phase of the study by choosing the probability of failing to find what is deemed "minimally important to detect" as being statistically significant, denoted by β, to be relatively small, typically not greater than 0.20. The value of $(1-\beta)\%$ is the power of the test. The power level reportedly used by Rigel in planning their study equals 70%.

Comments on Weinblatt et al article published in *Arthritis and Rheumatism* , November, 2008

1. In the "**Statistical analysis**" section on page 3311, the authors state that " Thirty-five evaluable patients in each group would provide 70% power to detect a treatment difference of 25% between the R788 groups and the placebo group at the 5% significance level." Firstly, one learns upon performing the sample size calculation that the 5% significance value used in this power calculation was one-sided rather than two sided. All hypothesis tests are two-sided. Had the 2-sided 5% significance level been used, 46 evaluable patients in each group would provide 70% power to detect a treatment difference of 25% between the R788 groups and the placebo group. Secondly, with such small sample sizes, an expert skilled in the art of applied statistics would usually recommend sample size estimates be calculated

using formula that are second-order correct. Had this been applied in this case, 53 evaluable patients in each group would provide 70% power to detect a treatment difference of 25% between the R788 groups and the placebo group {Reference Fleiss, Table A.3). In fact, the study only had 50% power to detect a treatment difference of 25% between the R788 groups and a placebo group at the 2-sided 5% significance level.

Summary of Rigel's presentation of study design

This study was designed to test each of the multiple comparisons between drugs with nominal p-values, and each test was performed at the 5% significance level with only 50% power to detect a difference of 25% between a R788 group and a placebo group. The presentation of the study design was not accurate and misleadingly. The authors' presentation that the power was 70% misleads the public to believe the study design was more robust than it actually was.

2. The ACR response rates and number of patients achieving response In **Table 2** on page 3313 agree with those contained in Rigel's December 13, 2007 Press Release. However, the **DAS28<2.6 outcome** data do not agree with the data contained in Rigel's December 13, 2007 Press Release. For example, with the December 13, 2007 Press Release Rigel reports that 17 of the 49 (35%) patients treated with the 100mg dose were DAS28 responders. But in Table 2 of the *Arthritis and Rheumatism* publication, 11 were DAS28 responders with a reported response rate of 26%. If the number of patients included in this analysis equals 43, then 11 of 43 corresponds to the reported 26% rate. The difference appears to be attributable to the *Arthritis and Rheumatism* article including only those who completed the study in the DAS28 success analysis (see **Figure 1** : Disposition of the patients, page 3312 of the *Arthritis and Rheumatism* article). Thus with the DAS28 outcome, it is not true that "All patients randomized into the study were included in the efficacy and safety analysis," as the

authors state on page 3311. This is in direct contrast to the December 13, 2007 analysis which included all patients.

Conclusion based on the *Arthritis and Rheumatism* article presentation of DAS28<2.6 outcome data

The analysis of the DAS28<2.6 success rates presented in the *Arthritis and Rheumatism* article did not include all patients. It appears that "non-completers" were omitted, thereby skewing the data and results being biased favoring R788.

3. **The Arthritis and Rheumatism publication falsely claimed that R788 significantly decreased certain biomarkers**.

On page 3314 the authors wrote "There was a significant decrease from baseline in serum IL-6 and MMP-3 levels in the 2 higher dose groups (100mg and 150mg) versus placebo at week 12 (P=0.05 for IL-6 level in the 100 mg group, P< 0.001 for IL-6 in the 150mg group, and P< 0.01 for MMP-3 level in both high-dose groups)." Using the summary statistics for these two outcome variables presented in **Table 3** on page 3313, I have performed the four two-sample t-tests (method per statistical analysis plan) comparing average change in the high dose groups to change in the Placebo group. The results are as follows: (i) Comparing average change of IL-6 level in the 100 mg group to the average change in the Placebo group, p=0.152, (ii) Comparing average change of IL-6 level in the 150 mg group to the average change in the Placebo group, p< 0.009, (iii) Comparing average change of MMP-3 in the 100 mg group to the average change in the Placebo group, p=0.125, (iv) Comparing average change of MMP-3 in the 150 mg group to the average change in the Placebo group, p=0.074.

Summary of the analyses of biomarker data presented in *the Arthritis and Rheumatism* publication

The reported p-values are false and in 3 of the 4 pair-wise comparisons the decrease was not statistically significant compared to Placebo. The faulty analyses presented R788 as being statistically superior when no such claim is warranted.

4. **Regarding difference between Mexico and U.S data,** on page 3313 the authors acknowledge that "the ACR20 did show a country effect…," but they do not provide a proper analysis to correct the distortion of the results due to the failure of accounting for country differences.

I declare under penalty of perjury that the foregoing is correct to the best of my knowledge and belief. This Declaration was executed the 23rd day of January, 2010, at Tucson, Arizona.

Daniel A. Bloch

Daniel A. Bloch, PhD
Emeritus Professor of Biostatistics
Stanford University

REFERENCES

Fleiss, J.L. *Statistical Methods for Rates and Proportions,* second edition. John Wiley & Sons, New York, 1981

Moses, L.E. *Think and Explain with Statistics.* Addison-Wesley, Menlo Park, California, 1986.

EXHIBIT 1

February 1, 2009

CURRICULUM VITAE

Daniel A. Bloch, Ph.D.

BIRTHPLACE & DATE: Palo Alto, CA; January 15, 1941

MARITAL STATUS: Married: Four children – born 1969, 72, 81, 85

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EDUCATION:

1963: B.S. Stanford University, Major: Statistics
1967: Ph.D. Johns Hopkins University, Statistics

ACADEMIC APPOINTMENTS:

1967 - 1968	Research Fellow, Biomathematics Department, Cornell University Medical School, New York, New York.
1967-1969	Research Associate, Sloan-Kettering Institute for Cancer Research, New York, New York.
1969-1970	Assistant Professor, Biomathematics Department, Cornell University Medical School, New York, NY Associate, Sloan-Kettering Institute for Cancer Research, New York, New York.
1970 - 1972	Assistant Professor of Mathematics, California State University, Sonoma, Cotati, California.
1984 - 1985	Statistician II. Division of Immunology, Department of Medicine, Stanford University, Stanford, California. Head Biostatistician for

	Arthritis, Rheumatism, and Aging Medical Information Systems (ARAMIS) and for Stanford Arthritis Center (SAC).
1985 - 1986	Statistician III, Division of Immunology, Department of Medicine, Stanford University School of Medicine, Stanford, CA
1986 - 1993	Senior Research Scholar, Department of Medicine, Stanford University School of Medicine, Stanford, California.
1993 - 1995	Acting Associate Professor, Department of Medicine and Department of Health Research and Policy, Stanford University School of Medicine, Stanford, California.
1995 – Sept. 2001	Associate Professor of Health Research and Policy, Division of Biostatistics, Stanford University School of Medicine, Stanford, California.
Sept. 2001 – present	Professor of Health Research and Policy, Division of Biostatistics, Stanford University, Stanford, California. Active Emeritus since February, 2007.

PROFESSIONAL APPOINTMENTS AND ACTIVITIES

1. Research and Teaching Assistant, Statistics Department, Johns Hopkins University, Baltimore, Maryland, 1963 – 1967.

2. Statistical Consultant, Stanford Linear Accelerator Center, Stanford, California, 1967.

3. Owner, Daniel A. Bloch, dba Land House Construction, General Contractor "B", License No. 292149, 1972-1984.

4. Member, Human Rights Committee, VA Cooperative Studies Center, 1986-1990.

5. Head biostatistician for AIDS Time-Oriented Health Outcome Study (ATHOS), 1989-1995.

6. Head biostatistician for the Stanford Arthritis Center (SAC), 1985-1996.

7. Head biostatistician for Arthritis, Rheumatism, and Aging Medical Information Systems (ARAMIS) and for Stanford Arthritis Center (SAC), 1985-2000.

8. Consultant on an ad hoc basis to pharmaceutical and biotechnical firms, including Merck-Serono, Novartis, Sorin Biomedical, NeuroPace, Veryan Medical, Arthrocare, Novate Medical, Intuitive Surgical, NeoTract, Procter and Gamble, Accuray, and others, 1987-present.

9. Consultant to the VA Cooperative Studies Coordinating Center, 1990-2007.

10. Member, Steering Committee, California Society of Addiction Medicine, 1990-1993.

11. Special government employee: consultant to FDA (including FDA statistical advisors panel), 1995-2006.

12. Member, Database Advisory Steering Panel, National Multiple Sclerosis Society, 1997-2003.

13. Member, Editorial Board for "Osteoarthritis and Cartilage", 1998-2008.

14. Member, VA Combined Monitoring Board, 2002-2005.

15. Member, Editorial Board for "Journal of Endovascular Therapy," 2001-present.

16. Member, numerous DSMBs for private industry and NIH grants, 1993-present.

SCHOLARLY PUBLICATIONS:

1. Peer Reviewed Journal Articles

1. **Bloch DA.** "A note on the estimation of the location parameter of Cauchy distribution." *J Am Stat Assoc*, 1966; **61**: 852-855.

2. **Bloch DA,** Watson GS. "A Bayesian study of the multinomial distribution." *Ann Math Stat*, 1967; **38**: 1423-1435.

3. **Bloch DA,** Gastwirth JL. "On a simple estimate of the reciprocal of the density function." *Ann Math Stat*, 1968; **39**: 1083-1085.

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7. Fries J, **Bloch DA,** Spitz P. "Cancer in rheumatoid arthritis: a prospective long-term study of mortality." *Am J Med*, 1985; **78**: 56-59.

8. Fries J, **Bloch DA,** Sharp J, McShane D, Patricia S, Gilbert B, Forrester D, Genant H, Gofton P, Richman S, Weissman B, Wolfe F. "Assessment of radiological progression in rheumatoid arthritis: a randomized controlled trial." *Arthritis Rheum*, 1986; **29(1)**: 1-9

9. Sherrer Y, **Bloch DA,** Mitchell D, Young D, Fries J. "The development of disability in rheumatoid arthritis." *Arthritis Rheum*, 1986; **29(4)**: 494-500.

10. Mitchell D, Spitz P, Young D, **Bloch DA,** McShane DJ, Fries JF. "Survival, prognosis, and cause of death in rheumatoid arthritis." *Arthritis Rheum*, 1986; **29**: 706-714.

11. Lane N, **Bloch DA**, Jones H, Marshall W, Wood PD, Fries JF. "Long-distance running, bone density, and osteoarthritis." *J Am Med Assoc*, 1986; **255(9)**: 1147-1151.

12. Fries J, Spitz P, Mitchell D, Roth S, Wolfe F, **Bloch DA** "Impact of specific therapy upon rheumatoid arthritis." *Arthritis Rheum*, 1986; **29(5)**: 620-627.

13. **Bloch DA** "Sample size requirements and the cost of a randomized clinical trial with repeated measurements." *Stat Med*, 1986; **5(6)**: 663-667.

14. Altman R, Asch E, **Bloch DA**, Bole G, Borenstein D, Brandt K, Christy W, Cooke TD Greenwald R, Hochberg M, Howell D, Kaplan D, Koopman W, Longley S, Mankin D, McShane DJ, Medsger T, Meenan R, Mikkelsen W, Moskowitz R, Murphy W, Rothschild B, Segal M, Sokoloff L, Wolfe R. "Development of criteria for the classification and reporting of osteoarthritis; classification of osteoarthritis of the knee." *Arthritis Rheum*, 1986; **29(8)**: 1039-1049.

15. Sherrer Y, **Bloch DA**, Strober S, Fries J. "Comparative toxicity of total lymphoid irradiation and immunosuppressive drug treated patients with intractable rheumatoid arthritis." *J Rheumatol*, 1987; **14(1)**: 46-51.

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17. Sherrer YS, **Bloch DA**, Mitchell DM, Roth SH, Wolfe F, Fries JF. "Disability in rheumatoid arthritis: comparison of prognostic factors across three populations." *J Rheumatol*, 1987; **14(4)**: 705-709.

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61. Sharp J, Wolfe F, Mitchell D, **Bloch DA**. "The progression of erosion and joint space narrowing scores in RA during the first twenty-five years of disease." *Arthritis Rheum*, 1991; **34(6)**: 660-668.

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64. Fries JF, Williams CA, **Bloch DA**. "The relative toxicity of non-steroidal anti-inflammatory drugs." *Arthritis Rheum*, 1991; **34(11)**: 1353-1360.

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66. Michel B, **Bloch DA**, Lane N, Fries J. "Effect of changes in weight-bearing exercise on lumbar bone mass after age fifty", *Ann Med*, 1991; **23**: 397-401.

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2. NON-PEER REVIEW PUBLICATIONS

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